

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of:

CRYSTAL et al.

Group Art Unit: unassigned

Application No.

Examiner: unassigned

Filing Date: August 27, 2003

For: GENETIC VACCINES DIRECTED  
AGAINST BACTERIAL EXOTOXINS

**INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Pursuant to 37 C.F.R. §§ 1.97 and 1.98, the references listed on the enclosed Form PTO-1449 and/or Substitute Form PTO-1449 ("Form 1449") are submitted for consideration by the Examiner in the examination of the above-identified patent application.

The full consideration of the references in their entirety by the Examiner is respectfully requested and encouraged. Also, it is respectfully requested that the references be entered into the record of the present application and that the Examiner place his or her initials in the appropriate area on the enclosed Form 1449, thereby indicating the Examiner's consideration of each of the references.

The submission of the references listed on the Form 1449 is for the purpose of providing a complete record and is not a concession that any reference listed thereon is prior art to the invention claimed in the patent application. The right is expressly reserved to establish an invention date earlier than the above-identified filing date in order to remove any reference submitted herewith as prior art should it be deemed appropriate to do so.

Further, the submission of the references is not to be taken as a concession that they represent art that is relevant or analogous to the claimed invention. Accordingly, the right to argue that the references are not properly within the scope of prior art relevant to an examination of the claims in the above-identified application is also expressly reserved.

The Information Disclosure Statement is being filed:

- ☒ **within** any one of the following time periods: (a) within three months of the filing date of a national application other than a continued prosecution application under § 1.53(d); (b) within three months of the date of entry of the national stage as set forth in § 1.491 of an international application; (c) before the mailing date of a first Office Action on the merits; or (d) before the mailing of a first Office Action after the filing of a request for continued examination under § 1.114.
- ☐ **after** (a), (b), (c) or (d) above, but before the mailing date of a final action under § 1.113, a Notice of Allowance under § 1.311, or an action that otherwise closes prosecution in the application, and includes *one* of:
- ☐ the Statement under § 1.97(e) (see "Statement under § 1.97(e)" below).  
*or*  
☐ the fee of \$180 set forth in § 1.17(p) (see "Fees" below).
- ☐ **after** the mailing date of a final action under § 1.113 or a Notice of Allowance under § 1.311, or an action that otherwise closes prosecution in the application, and on or before payment of the issue fee, and includes the Statement under § 1.97(e) (see "Statement under § 1.97(e)" below), and the fee of \$180 as set forth in § 1.17(p) (see "Fees" below).
- ☐ **after** the mailing date of a Notice of Allowance under § 1.311, and on or before payment of the issue fee, and **within** thirty days of receiving each item of information contained in the Information Disclosure Statement, and includes the Statement under § 1.704(d) (see "Statement under § 1.704(d)" below), and the fee of \$180 as set forth in § 1.17(p) (see "Fees" below).
- NOTE: This is for original applications except applications for a design patent, filed on or after May 59, 2000, wherein a paper containing only an Information Disclosure Statement in compliance with §§ 1.97 and 1.98 is being filed.

#### Copies of the References

- ☒ Copies of the non-U.S. patent references listed on the enclosed Form 1449 are enclosed herewith. Attached to each reference not in the English language is a concise explanation of its relevance pursuant to § 1.98(a)(3).
- ☐ A copy of a foreign search report from a counterpart foreign application is enclosed herewith.
- ☐ The references listed on the enclosed Form 1449 were previously identified in the parent application(s) of the present application, and a copy of each reference was furnished at that time. Accordingly, additional copies of the references are not submitted herewith, so as not to burden the file with duplicate copies of references.

The Examiner is respectfully requested to carefully review the references in accordance with the requirements set out in the Manual of Patent Examining Procedure. In accordance with § 1.98(d), the details of the parent application(s) relied upon for an earlier filing date under 35 USC § 120 in which copies of the reference were previously furnished are set out below:

U.S. APPLICATIONS		STATUS (CHECK ONE)		
U.S. APPLICATIONS	U.S. FILING DATE	PATENTED	PENDING	ABANDONED
1. 0 /				
2. 0 /				
3. 0 /				

**Statement under § 1.97(e)**

- ☐ The **undersigned** hereby states that each item of information contained in the Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign patent application not more than three months prior to the filing of the Information Disclosure Statement.
- ☐ The **undersigned** hereby states that no item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign patent application, and, to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in the Information Disclosure Statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the Information Disclosure Statement.

**Statement under § 1.704(d)**

- ☐ The **undersigned** hereby states that each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and that this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.

**Fees**

- ☒ No fee is owed by the applicant(s).
- ☐ The **IDS Fee of \$180** under § 1.17(p) is enclosed herewith.

**Method of Payment of Fees**

- ☐ Attached is a check in the amount of \$ .
- ☐ Charge Deposit Account No. 12-1216 in the amount of \$180.00. (A duplicate copy of this communication is enclosed for that purpose.)

In re Appln. of CRYSTAK et al.  
Attorney Docket No. 216474

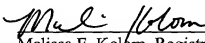
**Authorization to Charge Additional Fees**

- ☒ If any additional fees are owed in connection with this communication, please charge Deposit Account No. 12-1216. (A duplicate copy of this communication is enclosed for that purpose.)

**Instructions as to Overpayment**

- ☒ Credit Account No. 12-1216.  
☐ Refund.

Respectfully submitted,



Melissa E. Kolom, Registration No. 51,860  
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Date: August 27, 2003

Substitute for form 1449A/B/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(Use as many sheets as necessary)</i>				<b>Complete if Known</b>	
				Application Number	
				Filing Date	August 26, 2003
				First Named Inventor	CRYSTAL, Ronald G.
				Group Art Unit	
Examiner Name					
Attorney Docket Number	216474				
Sheet	1	of	2		

U.S. PATENT DOCUMENTS								
Examiner Initials <sup>1</sup>	Cite No.	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Class	Subclass	Filing Date If Appropriate
		Patent Number	Kind Code					
	AA	6,083,716		Wilson et al.	07-04-2000			
	AB	6,348,450		Tang et al.	02-19-2002			
	AC	6,500,641		Chen et al.	12-31-2002			

FOREIGN PATENT DOCUMENTS										
Examiner Initials <sup>1</sup>	Cite No.	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Class	Subclass	Translation	
		Office	Number	Kind Code					Yes	No*

OTHER - NON PATENT LITERATURE DOCUMENTS							
Examiner Initials <sup>1</sup>	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-isue number (s), publisher, city and/or country where published.	Translation				
			Yes	No*			
	AD	BELL et al., <i>Emerg. Infect. Dis.</i> , 8 (2), 222-225 (February 2002).					
	AE	CIESLAK et al., <i>Emerg. Infect. Dis.</i> , 5 (4), 552-555 (July-August 1999).					
	AF	FARINA et al., <i>J. Virol.</i> , 75 (23), 11603-11613 (December 2001).					
	AG	GU et al., <i>Vaccine</i> , 17, 340-344 (1999).					
	AH	IACONO-CONNORS et al., <i>Infect. Immun.</i> , 59 (6), 1961-1965 (June 1991).					
	AI	INGELSBY et al., <i>JAMA</i> , 287, 2236-2252 (2002)					
	AJ	IVINS et al., <i>Eur. J. Epidemiol.</i> , 4, 12-19 (1988)					
	AK	IVINS et al., <i>Vaccine</i> , 11-12, 1141-1148 (July 1998).					

\* A concise statement of relevance is being submitted in lieu of a translation. 37 CFR 1.98(a)(3).

+ An English-language equivalent/patent, or an English-language abstract, or an English-language version of the search report or action by a foreign patent office in a counterpart foreign application indicating the degree of relevance found by the foreign office is being submitted in lieu of a concise explanation of relevance under 37 CFR 1.98(a)(3).

Examiner SigNat.		Date Considered	
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<sup>1</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

**Complete if Known**

August 26, 2003

CRYSTAL, Ronald G.

Examiner Name \_\_\_\_\_

Attorney Docket

216474

Sheet

2

○

2

## OTHER - NON PATENT LITERATURE DOCUMENTS

[illegible]

\* A concise statement of relevance is being submitted in lieu of a translation. 37 CFR 1.98(a)(3).

+ An English-language equivalent/patent, or an English-language abstract, or an English-language version of the search report or action by a foreign patent office in a counterpart foreign application indicating the degree of relevance found by the foreign office is being submitted in lieu of a concise explanation of relevance under 37 CFR 1.98(a)(3).

Examiner SigNat.		Date Considered	
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